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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,078	09/24/2001	Rafael Pi Subirana	H-3734 PCTUS	9173

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EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1616

DATE MAILED: 11/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,078

Applicant(s)

PI SUBIRANA ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1616

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondenc address --**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other:

First Office Action on the Merits

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recites compounds not described by the present specification. For example, claim 10 recites a process for the production of sterol phosphates of formula II that optionally contains one or more double bonds. However, the present specification discloses 5,8-dienes of formula I (see page 2, lines 5-17) but lacks written description of compounds of formula II as recited by the instant claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by

Cremllyn et al.

Cremllyn et al. teach ergosteryl dihydrogen phosphate and lanosteryl dihydrogen phosphate (see page 2309, 2nd col., lines 18 and 27). The compounds taught by the reference are encompassed by the instant claims.

5. Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by

Ramirez et al.

Ramirez et al. teach stigmasterol dihydrogen phosphate and ergosteryl dihydrogen phosphate (see page 1419, compound #s 5 and 6). The compounds taught by the reference are encompassed by the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okamoto and Cremllyn et al. or Ramirez et al. in combination

Okamoto et al. teach the synthesis of alkyl dihydrogenphosphate by reaction of an alcohol, such as cholesterol, with a polyphosphate (see the entire article, especially page 3393, col. 1).

Cremlyn et al. and Ramirez et al. teach alcohols, such as cholesterol, ergosterol, lanosterol and stigmasterol and phosphates thereof (see Cremlyn et al., page 2309, 2nd col., lines 18 and 27 and Ramirez et al., page 1419, compound #s 1, 5 and 6).

Based on the teachings of Okamoto and the level of skill of the ordinary artisan in the art at the time of the invention, it would have been obvious to utilize any alcohol, including those taught by Cremlyn and Ramirez, in the process of Okamoto with the reasonable expectation of obtaining the desired phosphates. The motivation is based on the teachings of Okamoto, analogous starting materials and the desire to obtain phosphate esters of ergosterol, lanosterol and stigmasterol.

Claims 13, 14 and 20 further differ by reciting specific temperature range.

Claims 18 and 19 further differ by reciting the use of heptane as the solvent.

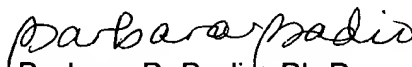
However, (a) both benzene and heptane are well known non-polar solvents and (b) change in reaction condition, such as reaction temperature, in order to optimize a reaction is routine in the chemical art. Thus, it would have been obvious to the skilled artisan to substitute heptane for benzene in the process taught by Okamoto with the reasonable expectation that the reaction would run to completion with the production of the desired end product. It would also be within the level of skill of the ordinary artisan to make changes in the reaction condition, such as changes in the reaction temperature, in order to change reaction rate, yield etc.

Telephone Inquiry

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
November 13, 2002